MEDICAID PHARMACY PRIOR AUTHORIZATION ADVISORY COMMITTEE
Final Meeting Summary
September 24, 2003

Introduction/Overview

The Medicaid Pharmacy Prior Authorization (PA) Advisory Committee met on September 24, 2003 to review two categories of drugs, namely, nonsedating antihistamines and calcium channel blockers.

Mark Moody, Administrator of the Division of Health Care Financing (DHCF) opened the meeting by reviewing the committee purpose and schedule for the day. Items covered included:

- The purpose of the meeting was to provide a brief background to the Wisconsin PA system, receive and review testimony of manufacturers and other interested individuals, present clinical information and the Department's recommendations for PA criteria and engage the PA Committee in a discussion of all these issues, with the goal of making recommendations to the Secretary.
- PA is a well established program authorized under federal law and used by Wisconsin Medicaid to ensure appropriate use of certain drugs and effect cost containment through clinically reviewed criteria. PA is one several benefits management strategies used by Medicaid, BadgerCare and SeniorCare to control drug costs. Other policies include generic substitution requirements, limited day supply, aggressive Maximum Allowable Cost pricing and recipient and provider profiling.
- PA is a cost effective means to encourage the use of inexpensive, clinically effective drugs. The objective of targeted PA is to shift a large portion of the drugs dispensed in a particular therapeutic class from high cost (usually brand name) drugs to lower cost (usually generic) drugs. To date, PA has been used on a limited basis for Medicaid, BadgerCare and SeniorCare.
- Though PA has been used on a limited basis in Wisconsin, other states use it on a broader scale. In fact, at least 46 of the 50 states have some form of a PA program for prescription drugs.
- State statute authorizes establishment of a PA Committee established by the Secretary of DHFS. The requirements for membership are two licensed physicians, two pharmacists and an advocate familiar with Medicaid drug issues – although the Secretary has committed to expand the committee to ensure the experiences and views of consumers and advocates are represented. Statutes also provide for a public process and ensure input from drug manufacturers – including both brand and generic drug makers.
- The 2003-05 Biennial Budget assumes savings of over $16 million (AF) in Medicaid/ SeniorCare pharmacy expenditures through PA of calcium channel blockers and non-sedating antihistamines.

Non-Sedating Antihistamines

DHFS Staff Recommendations

DHCF staff presented the PA recommendations for nonsedating antihistamine drugs listed below.

All individuals should be on an over-the-counter non-sedating antihistamine – regular or decongestant. As the medical literature supports the therapeutic interchangeability of products in this class, grandfathering patients on non-preferred brand products in not necessary. Therefore, the system should ask the following question:

Has this patient been tried on and failed or had an adverse reaction to a generic nonsedating antihistamine product, with or without a decongestant?

- If yes, approve the PA for up to 365 days.
- If no, return the PA with the following message, "Your PA request requires additional information. Please submit your request on paper with complete clinical documentation."

Testimony

The first person to give testimony was Dr. Michael Ostrov, Medical Director of Group Health Cooperative. His comments included:

- PA has been used by managed-care organizations for many years.
- There is no reason Medicaid should not also take advantage of the use of PA to contain costs while assuring quality.
- The Department's recommendation on nonsedating antihistamine drug is one that he would support.

The manufacturers of brand-name nonsedating antihistamine drugs gave testimony next. The drugs discussed and manufacturers presenting included:

Drug	**Manufacturer**
Zyrtec	Pfizer
Clarinex	Schering
Allegra	Aventis

Major points made by the manufacturers were:

- Zyrtec is the only nonsedating antihistamine drug approved for children ages six months through two years. Manufacturers of Clarinex and Allegra have submitted data on efficacy

of their products in children under two years of age to the Food and Drug Administration (FDA), but no final decision is anticipated before the end of the year.

- Schering emphasized that Clarinex, but not Claritin, is indicated for perennial allergic rhinitis and chronic urticaria (hives).
- Schering and Aventis emphasized their products reduced somnolence side effects compared to other products.

No consumers or other parties offered testimony about these drugs.

Committee Discussion

The committee then discussed non-sedating antihistamine drugs. The committee agreed with the DHCF recommendation but expressed some concern about children under the age of two since Zyrtec is the only nonsedating antihistamine with FDA approval for children ages six months through two years. More specifically, comments included:

- Dr. Fleming: Expressed some concern for children under two but otherwise saw starting with loratadine before getting other drug as reasonable.
- Mr. Maike: Concerned about high-risk population who may need something other than nonsedating antihistamine and would they be required to start with loratadine. Interested in switch ratios.
- Dr. Fedderly: Relatively similar products. All are good. There was some questioned about the sedation issue for young children with special-needs and children with sleep disorders
- Mr. Frasier: Since this drug is available over-the-counter, how would it be treated in SeniorCare? (It would not be covered but would be available OTC for less than the SeniorCare brand medication cost.)
- Dr. Heersma: Children under two often are given first generation antihistamines without problem. Parents are generally accepting of using first generation antihistamines in young children since sleeping may be desirable for these young children. There should be no grandfathering. These drugs are all similar.
- Ms. Smelser: Supports the DHCF recommendation. Medicaid co-pay would be less and that could be a substantial savings to the Medicaid population. In SeniorCare there should be consumer education about over-the-counter medications.

The committee agreed with the DHCF recommendation but expressed some concern about children under the age of two since Zyrtec is the only nonsedating antihistamine with FDA approval for children ages six months through two years.

Follow-up Note
The Division did some additional work and discovered that of the 109,582 children ages two and under on Medicaid in 2002, 875 received liquid Zyrtec and 103 received liquid loratadine. These are the only nonsedating antihistamines with liquid dosage forms.

The committee adjourned for lunch.

Calcium Channel Blockers

The afternoon session was devoted to discussing calcium channel blocker drugs.

DHFS Recommendations

DHCF staff presented the PA recommendations for calcium channel blocker drugs listed below.

Individuals should all be on a generic calcium channel blocker unless they are being treated for a condition other than hypertension. No general "grandfathering" is necessary. Therefore, the system should ask the following questions:

Is this calcium channel blocker drug being used to treat a condition other than hypertension?

- If yes, approve the PA for up to 365 days.
- If no, then ask:
  Has this patient been tried on and failed or had an adverse reaction to a generic calcium channel blocker drug?
- If yes, approve the PA for up to 365 days.
- If no, return the PA with the following message, "Your PA request requires additional information. Please submit your request on paper with complete clinical documentation."

Testimony

The only manufacturer of a brand-name calcium channel blocker drug registered to give testimony was Pfizer, which makes Norvasc. Dr. Wilson, a cardiologist at Mayo, represented Pfizer. His major points were:

- Long acting drug (no need for a sustained release product).
- Calcium channel blockers should be used with caution on patients with heart failure as it may make them worse, but a study of Norvasc used in patients with severe heart failure did not increase morbidity or mortality and decreased cardiac events in patients with non-ischemic cardiomyopathy.
- When used to treat hypertension, calcium channel blockers are seldom used alone.

No consumers or other parties offered testimony about these drugs.

Committee Discussion

The committee then discussed calcium channel blocker drugs. Major points made by the committee included:

- Dr. Fleming: If the patient is stabilized on brand-name product, they should remain on it. It would be difficult to convince doctors of the value of switching stabilized patients to another drug. This would require at least 2-3 additional office visits to assure blood pressure remained stable. Diuretics should be used before calcium channel blocker drugs. Using a generic as the first calcium channel blocker drug where there are no contraindications would be alright.
- Mr. Maike: The drug cost savings may be negated by the full cost of moving the patient from one drug to another. What is the cost per day and how many people currently on the brand name product would meet the criteria for being treated for something other than hypertension?
- Dr. Fedderly: We should follow the traditional cascade therapy. That is, patients being treated for hypertension should first be tried on a diuretic and then where appropriate, a calcium channel blocker drug. The real savings would be in having patients take generic diuretics first. The recommendation is more one of going beyond the class of calcium channel blocker drugs, almost into disease management for hypertension.
- Mr. Frazier: Grandfathering stabilized patients should occur. Cascade therapy and looking at diuretic use should be considered.
- Dr. Heersma: Expressed being in favor of grandfathering.
- Ms. Smelser: Expressed concern about costs associated with switching patients to another product. Also felt we should go beyond just calcium channel blocker drugs for treatment of hypertension. Recommended encouraging prescribers to try a diuretic first and distributed a summary of the ALLHAT study which compared chlortalidone (Hygroton) with lisinopril (Zestril) and amlodipine (Norvasc). Neither lisinopril nor amlodipine was found to be superior to chlortalidone in preventing coronary deaths or increasing survival. (Dr. Wilson disputed the findings of the ALLHAT study.)

In general, the consensus of the group was that this was a very complicated issue and we should not proceed with requiring PA of brand name calcium channel blocker drugs at this time. The committee was open to looking at this issue again in the future.

The meeting adjourned at 3:00 p.m.